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August 12, 2005

Mr. Arthur Neal
Director, Program Administration
National Organic Program
USDA-AMS-TMP-NOP
1400 Independence Ave., SW
Room 4008-So., Ag Stop 0268
Washington, DC 20250

**Re: Docket No. TM-04-07, Submission of Comments in Response to ANPRM
Concerning NOP Sunset Review**

Dear Mr. Neal:

The Enzyme Technical Association ("ETA") submits its response to the Advance Notice of Proposed Rulemaking ("ANPRM") (Docket No. TM-04-07) requesting comments regarding the allowed use of synthetic and non-synthetic substances in organic production and handling, which shall expire on October 21, 2007, as required by the Organic Foods Production Act of 1990 ("OFPA"). Cf. 70 Fed. Reg. 35,177 (June 17, 2005). ETA believes that the continued allowance of the enzymes identified for use in "organic products" in the National List of Allowed and Prohibited Substances ("National List") is appropriate.

OFPA authorizes the establishment of the National List of exempted and prohibited substances, and these exemptions and prohibitions granted under OFPA are required to be reviewed by the National Organic Standards Board ("NOSB") every 5 years. The Secretary of Agriculture has authority under OFPA to renew these exemptions and prohibitions. If they are not reviewed by the NOSB and renewed by the Secretary within 5 years, their authorized use or prohibition expires.

Namely, a synthetic substance currently allowed for use in organic production will no longer be allowed after October 21, 2007; likewise, a non-synthetic substance currently prohibited from use in organic production will be allowed after October 21, 2007. Furthermore, a synthetic or non-synthetic substance currently allowed for use in organic handling will be prohibited after October 21, 2007. Cf. 70 Fed. Reg. 35,177, 35,177 (June 17, 2005). ETA sees no reason why the Secretary of Agriculture should not renew the use of enzymes in organic products.

ETA has spent a considerable amount of time researching and analyzing the use of various enzymes in organic products, and the association has provided information to the NOSB for the purpose of placing a number of enzymes on the National List. For

example, enzymes derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria are listed on the National List as nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic." See 7 C.F.R. 205.605(a).

The Secretary of Agriculture should renew the exemption for the use of enzymes, as currently listed in 7 C.F.R. § 205.605(a), for the following three reasons: (1) enzymes do not have an adverse impact on humans or the environment, (2) enzymes are essential for organic production, and (3) enzymes are compatible with organic production practices. See 7 U.S.C. § 6517(c)(1)(A) (listing the statutory guidelines for prohibitions or exemptions on the National List). ETA discusses these reasons in further detail below.

Enzymes Do Not Have an Adverse Impact on Humans or the Environment

Enzymes do not have an adverse impact either on humans or on the environment. Enzymes do not cause environmental contamination during their manufacture, use, misuse, or disposal. *Cf.* 7 U.S.C. § 6518(m)(3). As protein substances, enzymes are not harmful to the environment. *Cf.* 7 U.S.C. § 6517(c)(2)(A)(i). Furthermore, enzymes do not contain EPA List 1, 2, or 3 inert ingredients. *Cf.* 7 U.S.C. § 6517(c)(1)(B)(ii).

Enzymes do not have a potential for a detrimental chemical interaction with other materials used in organic farming systems. *Cf.* 7 U.S.C. § 6518(m)(1). Enzymes do not cause adverse biological or chemical interactions in agro-ecosystems. *Cf.* 7 U.S.C. § 6518(m)(5). Furthermore, enzymes do not cause detrimental physiological effects on soil organisms, crops, or livestock, as they are protein catalysts that are ubiquitous throughout natural systems, including the human body. *Cf.* 7 U.S.C. § 6518(m)(5).

There is no toxic or other adverse action of enzymes or their breakdown products. *Cf.* 7 U.S.C. § 6518(m)(2). Nor is there an undesirable persistence or concentration of enzymes or their breakdown products in the environment. *Cf.* 7 U.S.C. § 6518(m)(2). Lastly, there are no regularly occurring harmful effects on human health; while certain individuals may be allergic to specific proteins when they are inhaled, such cases are unusual and seldom-seen occurrences. *Cf.* 7 U.S.C. § 6517(c)(1)(A)(i); 7 U.S.C. § 6517(c)(2)(A)(i); 7 U.S.C. § 6518(m)(4).

Enzymes Are Essential for Organic Production

Enzymes are essential for organic production. ETA notes that enzymes are neither formulated nor manufactured by a chemical process. Furthermore, enzymes are not formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources. Enzymes are in fact created by naturally occurring biological processes in that they are created through a fermentation process or are extracted from food plants and animals. *Cf.* 7 U.S.C. § 6502(21).

There are no wholly natural substitute products for enzymes in that the enzyme *is* the natural product. *Cf.* 7 U.S.C. § 6517(c)(1)(A)(ii). Enzymes are produced by

microorganisms or are extracted from food plants and animals, and as such, enzymes used in handling are not synthetic, but not organically produced. *Cf.* 7 U.S.C. § 6517(c)(1)(B)(iii). There are no alternative substances. *Cf.* 7 U.S.C. § 6518(m)(6). There are no other practices that would make enzymes unnecessary. *See id.* Thus, enzymes are essential for organic production.

Enzymes Are Compatible with Organic Production Practices

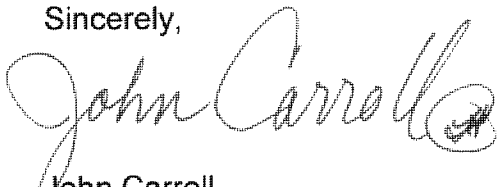
ETA further notes that enzymes are compatible with organic production practices. Because enzymes are naturally occurring protein catalysts, their use is consistent with organic farming and handling. *Cf.* 7 U.S.C. § 6517(c)(1)(A)(iii); 7 U.S.C. § 6517(c)(2)(A)(ii). Enzymes are also compatible with a system of sustainable agriculture. *Cf.* 7 U.S.C. § 6518(m)(7). Enzymes are used in production, and they do not contain an active synthetic ingredient in the following categories:

- a. Copper and sulfur compounds;
- b. Toxins derived from bacteria;
- c. Pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals;
- d. Livestock parasiticides and medicines; or
- e. Production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners.

See 7 U.S.C. § 6517(c)(1)(B)(i).

In summary, enzymes do not have an adverse impact either on humans or on the environment; enzymes are essential for organic production; and enzymes are compatible with organic production practices. For these reasons, as discussed above, the Secretary of Agriculture should renew the exemption for enzymes provided in 7 C.F.R. § 205.605(a). Enzymes are critical to the handling and production of a variety of organic agricultural products, and the expiration of their exempt status would disrupt well-established and accepted organic production and handling practices. ETA therefore seeks the continued exemption of enzymes as nonsynthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic."

Sincerely,



John Carroll
Chair